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In re Application of  
GERMINO et al  
Serial No.: 09/904,968 : Decision on Petition  
Filed : 13 JULY 2001  
Attorney Docket No.: JHU1680-2

This letter is in response to the Petition under 37 C.F.R. 1.144 filed on 20 October 2006. The delay in acting upon this petition is regretted.

**BACKGROUND**

The petition filed under 37 CFR 1.144 requests reconsideration of the restriction requirement mailed 23 May 2002. The restriction requirement mailed 23 May 2002 divided claims 1-67 into 45 groups and then required an election of a single sequence within every group.

After numerous communications, Applicants elected a group and a single primer pair, nested primer pair and polymorphism within that primer pair with traverse. The examiner considered the traversal and made the restriction requirement final in the Office action mailed 29 January 2004.

The claims have been amended by applicants and examined by the Office several times.

As of the most recent amendment, filed 10 October 2006, claims 5-15, 17, 26-27, 38, 43, 45-47, 53-54, 62-75 and 77 have been cancelled, leaving claims 1-4, 16, 18-25, 28-37, 39-42, 44, 48-52, 55-61, 76 and 78 pending. Of those pending, only claims 18, 30, and 58 have been withdrawn from consideration in their entirety. In addition, a sequence restriction was set forth and SEQ ID NO: 5, 6, 21, and 22 which are recited in the alternative in claims 1, 25, 44, and 60 are also withdrawn from prosecution. For those claims, elected primer pairs SEQ ID NO: 3 and

4 and SEQ ID NO: 19 and 20 were considered. The relevant features of the pending claims are described as follows:

Independent Claim 1 is directed to a product and has been amended to require a set of eight primers that flank 8 specific positions in polycystic kidney disease-associated protein-1 (PKD-1) gene. Claims 2-4, 16, and 19 depend, directly or indirectly, upon claim 1. Claim 18 depends from canceled claim 17.

Claim 1 requires that two primers are selected from SEQ ID NO: 3, 4, 5, and 6. Primers of SEQ ID NO: 3 and 4 were elected and are under examination. Primers of SEQ ID NO: 5 and 6 are treated as withdrawn, there being no allowable linking claim and there being no allowable claim directed to the elected species.

Claim 1 further requires two primers selected from SEQ ID NO: 19, 20, 21, and 22. Primers of with SEQ ID NO: 19 and 20 were elected and are under examination. Primers of SEQ ID NO: 21 and 22 are treated as withdrawn, there being no allowable linking claim and there being no allowable claim directed to the elected species.

Independent claim 20 is directed to a polynucleotide that comprises ten positions spanning residues 3335-3337 of PKD1 polynucleotide set forth in SEQ ID No 1. Claims 21-24 depend from claim 20.

Independent claims 25, 44 and 60 are directed to three methods which employ a nested amplification process which utilizes two sets of primers. Claims 28-37, 39-42, 48-52, 55-59, 61, 76 and 78 all refer back, directly or indirectly, to claims 25, 44 or 60, however the method claims do not require a set of eight primers.

This petition was filed 20 October 2006, before the filing of a Notice of Appeal, and is thus considered timely.

## DISCUSSION

The petition has been considered carefully in terms of the claim set as it is now pending before the Office. The petition requests rejoinder of original groups 1-43, but because those groups are apparently not present in the current claim set, this request is dismissed.

The Office has already examined together claims 1-4, 16, 19-25, 28-29, 31-37, 39-42, 44, 48-52, 55-61, 76 and 78 pending to the extent that these claims read upon elected primer pairs (SEQ ID No 3 and 4; SEQ ID NO 19 and 20). No claim is currently in condition for allowance. Claims 18, 30, and 58 are currently withdrawn from consideration. Claims 30, and 58 depend originally from claims currently under examination and as such, are the only subject matter which is now being restricted apart from the claim set. Claim 18 is currently indicated as withdrawn but depends from a canceled claim.

MPEP 803 discusses the two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent (see MPEP § 802.01, § 806.06, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(j)); and
- (B) There would be a serious burden on the examiner if restriction is not required (see MPEP § 803.02, § 808, and § 808.02).

In this particular instance, the Office will not maintain its position that concurrent examination of all claims pending at the time this petition was filed, 20 October 2006, would pose a serious burden because the two claims withdrawn from examination, claims 30 and 58, depend from and require all the limitations of claims currently under examination. Without a showing of serious burden, maintaining a restriction requirement between the claims currently under examination and withdrawn claims 30 and 58 would not be proper.

## **DECISION**

The petition filed under 37 CFR 1.144 is **GRANTED-IN-PART** to the extent that currently pending claims 30 and 58 will be rejoined for examination with claims 1-4, 16, 19-25, 28-29, 31-37, 39-42, 44, 48-52, 55-61, 76 and 78 pending.

The petition is **dismissed** with regard to the request to rejoin Groups 1-43, because no claims currently pending correspond with those original groups.

Should the claims directed to the elected pairs of primers of SEQ ID Nos 3 and 4 and SEQ ID Nos 19 and 20 become allowable, and should those claims recite in the alternative the non-elected primer pairs of SEQ ID Nos 5 and 6 and SEQ ID Nos 21 and 22, examination may be extended to the non-elected primer pairs of SEQ ID Nos 5 and 6 and SEQ ID Nos 21 and 22, per MPEP 803.02.

**The application will be forwarded to the Examiner to consider the papers filed on 10 October 2006 and to prepare an action consistent with this decision.**

Should there be any questions regarding this decision, please Quality Assurance Specialist/Program Manager Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 571-273-8300.



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